

FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

**§ 405.213 Re-evaluation of a device categorization.**

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by HCFA only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor HCFA's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both HCFA and the sponsor of its decision.

(c) *Request to HCFA.* If the FDA does not agree to recategorize the device, the sponsor may seek review from HCFA. A device sponsor must submit its request in writing to HCFA. HCFA obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. HCFA reviews all material submitted by the sponsor and the FDA's recommendation. HCFA reviews only information in the FDA record to determine whether to change the categorization of the device. HCFA

issues a written decision and notifies the sponsor of the IDE and the FDA.

**§ 405.215 Confidential commercial and trade secret information.**

To the extent that HCFA relies on confidential commercial or trade secret information in any judicial proceeding, HCFA will maintain confidentiality of the information in accordance with Federal law.

**Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans**

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

**§ 405.301 Scope of subpart.**

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

**§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.**

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or